

PATENT/Docket No. 01453.US1
Appl. No. 10/776,837
Filing Date: February 11, 2004
Reply to Office action of January 6, 2005

REMARKS/ARGUMENTS

I. Preliminary Remarks

Claims 1 to 10 are pending in the Application. Claims 1, 5, and 9 are rejected. Claims 2-4, 6-8, and 10 are objected to. Claims 5 and 9 are amended herein. The amendments are made for clarity, and support for these changes is found throughout the specification. The amendments do not include new matter. Reconsideration and withdrawal of the rejections and objections are solicited for the reasons set out below. An amendment to the specification is made to correct a clerical error. This response is timely filed with an Extension of Time.

II. Amendment to the Specification.

In the specification, on page 8, line 29, in the paragraph beginning with "The compounds of the present invention may also contain unnatural proportions of atomic isotopes..." a typographical error was found. Applicants respectfully request the following amendment:

"For example, the compounds may be radiolabeled with radioactive isotopes, such as for example tritium (3 H), iodine-125 (¹²⁵I)-(125I) or carbon-14 (14C). All isotopic variations of the compounds of the present invention, whether radioactive or not, are intended to be encompassed within the scope of the present invention."

This amendment does not add new material, and is made to correct a clerical error.

III. Patentability Arguments

A. The Rejection of Claim 1 under 35 U.S.C. §112, First Paragraph, May Properly Be Withdrawn.

Claim 1 was rejected under 35 U.S.C. §112, First Paragraph, "as failing to comply with the enablement requirement." The Examiner states that "the claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Applicants respectfully traverse this rejection.

Examiner states that "the expression substituted is employed with considerable abandon throughout claim 1 with no indication given as to what the substituents really are. One should be able, from a reading of the claims, to determine what that claim does or does not encompass."

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However, Applicants respectfully submit that a specification only needs to "supply the novel aspects of an invention in order to constitute adequate enablement." *Genentech, Inc. v. Novo Nordisk*. 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), cert. denied. 522 U.S. 963 (1997) (emphasis added). The omission of minor details does not cause a specification to fail to meet the enablement requirement. *Id.* In the instant case, a novel aspect of the invention is found in claim 1, which provides for compounds of a genus of thiophene substituted triazoles in which R₁ is thiophene and R₂ to R₄ represent non-heterocyclic groups. In this regard, Applicants submit that the specification provides sufficient guidance and working examples relating to this novel aspect. The claim clearly defines what is covered, and the substituents referred to in the claim are clearly defined in the specification (See pages 2-6). The application contains examples of two compounds within the scope of Claim 1 which are fully exemplified (Compounds 48 and 49). The Applicants also provide generic chemistry describing how to prepare compounds of this genus (See pages 9-10). Applicants recognize that those skilled in the art may conduct additional experimentation in order to produce all of the compounds in the claims. However, Applicants respectfully submit that such experimentation is not undue and can be achieved by following routine procedures as outlined in the specification.

In the discussion of the factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue, the Examiner has made several statements without documentary evidence to support such statements. For example, Examiner stated that "substituents may convert from less stable to more stable forms;" that "substituents often change back to the original compound during drug manufacture;" and "unpredictability in the art." However, Examiner has provided no evidence that such is the case for the compounds of the present invention. As presented in the Manual of Patent Examining Procedure (Section 2144.03A), "*Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("The Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). As stated above, Applicants submit that the specification provides sufficient guidance and working examples relating to the novel compounds of the claims.

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Claim 1 provides for a compound of Formula I wherein R₁ is thiophene; R₂ and R₄ are independently selected from the group H, C₁-C₈ alkyl, phenyl, substituted phenyl, benzyl, and substituted benzyl; and R₃ is H, C₁-C₈ alkyl, cycloalkyl, or aryl. The claim clearly defines what is covered, and the substituents referred to in the claim are clearly defined in the specification (See pages 2-6). The Applicants also provide generic chemistry describing how to prepare compounds of this genus (See pages 9-10). Applicants respectfully submit that experimentation required to make or use the invention is not undue and can be achieved by following routine procedures as outlined in the specification.

In view of the foregoing, Applicants respectfully submit that one skilled in the art can make the claimed compounds without undue experimentation. Thus, the rejection of Claim 1 under 35 U.S.C. 112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

B. The Indefiniteness Rejections of Claims 1, 5, and 9 under 35 U.S.C. §112, Second Paragraph, May Properly Be Withdrawn.

The Examiner rejected claims 1, 5, and 9 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Applicants respectfully disagree and submit that the claims are not indefinite.

The Examiner stated "The expression substituted in claim 1 are indefinite." Applicants submit that the term substituted is a commonly used expression, well-understood in the art. The substituents are defined in the specification (See pages 2 to 6).

The Examiner stated that Claims 5 and 9 are indefinite because the expression 'containing' allows for the inclusion of other active ingredients. However, the compounds of the present invention are novel. Thus, compositions containing them are novel. The addition of another ingredient, whether active or inert, to the composition does not negate the novelty of a composition containing compounds of the present invention. Applicants are therefore entitled to the claims that encompass their novel compounds in a composition.

The Examiner stated that "Claims 5 and 9 are not proper composition claims because they fail to recite an inert carrier." However, an object of the application is use of the compounds to control parasitic infections in human and animal populations (See specification pages 1-2

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discussion of technology description; and pages 7-8 discussion of prodrugs). One skilled in the art would know that a use of the compounds of the present invention to control parasitism may entail using the compounds in a pharmaceutical composition. Applicants maintain that given the volumes available to one skilled in the art of formulations, (eg, Remington: The Science and Practice of Pharmacy, (formerly called Remington's Pharmaceutical Sciences), Mack Publishing Co.) that reciting an inert carrier is unnecessary for inclusion in the claims.

For the foregoing reasons, Applicants respectfully submit that the rejection of claims 1, 5, and 9 under 35 U.S.C. §112, second paragraph, for indefiniteness may be properly withdrawn. Applicant respectfully requests withdrawal of this rejection.

C. Allowable Subject Matter.

Examiner stated that Claims 2 to 4, 6 to 8, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants respectfully submit that claims 1, 5, and 9 are in condition for allowance based on the remarks, arguments, and amendments presented herein. Thus, amendments to Claims 2 to 4, 6 to 8, and 10 are not needed. Applicants respectfully submit that the objection of claims 2 to 4, 6 to 8, and 10 may be properly withdrawn. Applicants respectfully request withdrawal of this objection.

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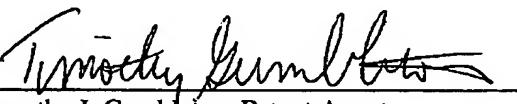
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IV. Conclusion.

In view of the amendments and remarks made herein, Applicants respectfully submit that Claims 1 to 10 are in condition for allowance and request expedited notification of same.

Respectfully submitted,



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